

K 011796

NOV 01 2001

**510 (k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
BAUSCH & LOMB ReNu MultiPlus^R
MULTI-PURPOSE SOLUTION**

1. Submitter Information

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14603-0450

Contact Person: Paul G. Stapleton
Director, Regulatory Affairs

Telephone Number: 716-338-8172

2. Device Name

Classification Name: Soft (hydrophilic) Contact Lens Solution

Proprietary Name: BAUSCH & LOMB ReNu MultiPlus Multi-Purpose
Solution

3. Predicate Devices

Alcon OPTI-FREE EXPRESS No Rub has been selected as the predicate device for Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution

4. Description of the Device

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is a sterile, isotonic solution that contains HYDRANATE^R (hydroxyalkyl phosphonate) as a protein deposit remover, poloxamine as a surface active agent and salts as tonicity and buffering agents; preserved with DYMED^R (polyaminopropyl biguanide) 0.0001%. The product is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. The sterile solution is contained in a plastic bottle and is labeled with a lot number and expiration date.

5. **Indications for Use**

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) and storage of soft (hydrophilic) lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

A series of preclinical and clinical studies were completed on this product and have previously been submitted under Premarket Approval Application P860023/S12, K974723 and K002823. No concerns were raised at the time of clearance.

In addition, the following studies have been completed:

Cleaning Studies

An in-vitro protein cleaning study was conducted with Groups 1 and 4 lenses artificially soiled with lysozyme. Deposited lenses were subjected to the no rub regimens for both the Test and Control based on labeled direction for use. These results indicated that both the Test and Control were statistically equivalent.

Microbiology Studies

A series of studies were completed to demonstrate the microbiological efficacy of ReNu MultiPlus Multi-Purpose Solution; these studies have previously been submitted in 510(k) clearances for K974723 and K-002823 and P860023/S12.

Additional microbiological testing has been completed based on the labeled directions for use. The results of the Stand-alone Procedure for Disinfecting Products, Primary Criteria and Regimen Test indicate that the performance criteria established by FDA have been met.

An additional microbiological test was completed employing the Stand-alone Procedure for Disinfecting Products, Primary Criteria that incorporated the use of organic soil. The results met the requirements of the test.

Clinical Studies

A multi-site randomized, controlled clinical study was conducted to evaluate the safety and efficacy of ReNu MultiPlus solution when used with a 5 second cleaning rinse prior to the disinfection cycle; no post-disinfection rinse was required. The Control solution was Alcon Opti-Free Express Multi-Purpose Disinfecting Solution No Rub which employed a 5 second cleaning rinse per side both before and after disinfection. Both regimens demonstrated clinically acceptable lens cleanliness. Safety and efficacy were demonstrated.

510(k) Premarket Notification
Bausch & Lomb ReNu MultiPlus® Multi-Purpose Solution

ReNu MultiPlus Multi-Purpose Solution is substantially equivalent to Alcon Opti-Free Express No Rub.

Biocompatibility Testing

ReNu MultiPlus Multi-Purpose Solution remains unchanged from the previously cleared product except for the Directions for Use. The labeling changes do not require new biocompatibility testing.

Substantial Equivalence

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution for use in a no rub regimen for lenses replaced at intervals of 30 days or less is substantially equivalent to Alcon OPTI-FREE EXPRESS No Rub.

The ReNu MultiPlus Multi-Purpose Solution will be sold in plastic bottles as a sterile solution; each bottle will be marked by a lot number and expiration date.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 01 2001

Mr. Paul G. Stapleton
Director, Global Regulatory Affairs
BAUSCH & LOMB
1400 N Goodman Street
P.O. Box 30450
Rochester, NY 14603-0450

Re: K011796

Trade/Device Name: Bausch & Lomb® ReNu MultiPlus® Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: September 14, 2001
Received: September 17, 2001

Dear Mr. Stapleton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive, flowing style.

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K011796

NOV 01 2001

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): K011796

Device Name: ReNu MultiPlus[®] Multi-Purpose Solution

Indications for Use:

ReNu MultiPlus Multi-Purpose Solution is indicated for use in daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter-Use ✓

[Signature]

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K011796

[Signature]